UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,412	02/19/2004	Andrea Grignani	SBC1030US	6449

9561 7590 01/17/2007

POPOVICH, WILES & O'CONNELL, PA
650 THIRD AVENUE SOUTH
SUITE 600
MINNEAPOLIS, MN 55402

EXAMINER	
CHANG, ROSIE YUH LOO	
ART UNIT	**PAPER NUMBER**
1762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,412	GRIGNANI ET AL.	
	Examiner	Art Unit	
	ROSIE YL CHANG	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *4,5,21-30 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-20, 31-40,42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/19/2004, 7/26/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I species (ii), claims 1-3, 6-20, 31-40 and 42 in the reply filed on Nov.13, 2006 is acknowledged. The traversal is on the ground(s) that the search and examination of the entire application cannot be made without serious burden (M.P.E.P.§ 803). This is not found persuasive because these inventions are independent or distinct for the reasons given previously and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02). Therefore, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(1)

Claims 1, 3, 37, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber el at (US 6,743,463).

Weber et al. ('463) teach a method for coating stent (col. 3, line 24) by depositing a formulation consisting of polymers and biological active materials (col.10, line 53-54) in the form of powder (col. 9, line 24-27) on selected surface area of stent (col. 5, line 37-40). Weber et al. ('463) disclose every limitation on the claims 1 and 3.

As for claims 37, 39:

Weber et al. ('463) teach that the active substance comprises immunosuppressant such as tacrolimus, i.e. FK509 (col. 12, line 1-2). The powder used in the coating comprised of particles having an average diameter from about 0.5 micron to about 250 micron (col. 10, line 36-37).

(2)

Claims 1, 3, 16, 19, 31, 32, 34 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwarz et al. (US 6,368,658).

Schwarz et al. ('658) teach a process for coating stent (col. 3, line 48) by depositing a formulation, which consists of polymers and biological active materials (col.2, line 10) in the form of particles, i.e., powder (col. 2, line12) on selected surface regions of stent (col. 2, line 6-7).

As for claims 16 and 19:

Schwarz et al. ('658) teach that stent may be loaded into a conventional fluidized bed chamber (col.9, line 41-45), in which air is introduced into a bed of the medical device from below while the coating material is sprayed onto the fluidized devices from above.

Schwarz et al. ('658) further teach that partial coating is accomplished (col. 11, line 56-58), for example, using known masking or similar techniques to result in the coating of predetermined stent segments.

As for claims 31 and 32:

Schwarz et al. ('658) further teach polymerization or treatment (col.11, line 46-52) of the stent surface using microwave, ultraviolet light, and thermal evaporation technique. Additionally, a protective layer can be applied as a top coating (col. 6, line 17-18).

(3)

Claims 1, 3, 34-38 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Verlee et al (US 2004/0,202,773).

Verlee et al. ('773) teach a method of loading (page 2, [0012]) the beneficial agent (note: beneficial agent (page 7, [0071]) includes active agents, polymers and solvents either alone or in combination) in either powder or paste form (page 5, [0058]) on a selected portion of the stent surface (page 5, [0053]). Thus, Verlee et al. ('773) teach every limitation of the claim.

As for claim 3:

The recitation of this claim is similar to that in step (ii) of claim 1 and is rejected on the basis set forth for claim1 discussed above.

As for claims 34 and 35:

Verlee et al. ('773) teach (page 5, [0055]) the stent can be in an expanded or unexpanded, i.e. contracted, state during the loading of active substances. The underlying structure of the stent can be virtually any structural design. Verlee et al. ('773) are silent concerning that the structure design of the stent is radially expanded or radially contracted; however, Verlee et al. ('773) teach the stents are expandable (page 1, [0007] and also the design of stents shown on Fig. 6, 7, and 9 of Verlee et al. ('773) are inherently radially expanded. Drug eluted stents usually are delivered to the coronary vasculature in their contracted state until a balloon portion thereon is positioned across an occlusive lesion. Once in position, the balloon is inflated to radially expand stent against the vessel wall. Therefore, after a radially expanded stent is loaded with active substance, it is then inherently subject to radial contraction.

As for claim 36 and 42:

Verlee et al. ('773) teach (page 5, [0055]) the surface of the prosthesis, i.e. stent can include one or more reservoirs or cavities formed therein. Verlee et al. ('773) further teach (page 13, [0121]) a polymer overcoat can be applied over the beneficial agent, i.e. active substance. Such a deposition configuration with cavities is particularly beneficial for minimizing delamination of the active substance.

As for claims 37, 38:

Verlee et al. ('773) teach the active substance is (page 5, [0061]) tacrolimus, i.e. FK 506. The stent (page 5, [0058]) is at least partially loaded with a drug, i.e. FK509 or composition of matter comprising drug, thus meeting the limitation of claims 37 and 38.

(4)

Claims 1,16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Dave (US2003/0,134,052).

Dave ('052) teaches an electrostatic process for coating stent (page 2, [0013]) by depositing a formulation, which consists of polymers and biological active materials (page 1, [0013]) in the form of powder on selected regions of stent surface.

Dave ('052) teaches (page 2, [0017]) the stent being exposed to the bed of active substance for transfer thereon. Dave ('052) further teaches (page 1, [0006]) the stent being exposed to the bed of active substance with application of pressure.

(5)

Claims 1, 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhong et al. (US 6,676,987).

Zhong et al. ('987) teach a process for precisely depositing the powder (col. 5, line 55-56) of active agents on the selected area and the other area of the surface of a stent (col. 2, line 45 and Fig. 2) by using a bubble jet printing head system (abstract). Zhong et al. ('987) teach (col. 7, line 25-58) applying a masking material on selected area of the coated stent and etching the stent surface area not covered by the masking material to remove the coating of the other area, thus meeting the limitation of claims 1 and 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(6)

Claims 2, 6, 8,10,12 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. ('463) in view of Nacker et al (US 5,925,402).

Weber et al. ('463) teach a method of spraying the powder (col. 3, line 59) of active agents on the entire surface (col. 3 line 44) of a stent, wherein the selected area

and the other area are coated in serial. Weber et al. ('463) fail to teach removing the active agent from the other area of the surface of said stent.

Nacker ('402) teaches a method of patterned coating on a substrate. The patterned images are produced by depositing a layer of coating powder on a substrate, directing a laser beam at the selected area of the coating layer so as to fuse an image on the selective area, and subsequently removing non-fused coating powder from remaining area of the coating layer (col. 1, line 21-27). The non-fused coating powder can be removed by compressed air (col.3, line 10), i.e. jets of fluid.

Since Weber et al ('463) teach a method of coating stent on selected area and Nacker ('402) teaches a method to remove the coating on the undesired area with jets of fluid, Nacker ('402) would have reasonably suggested to improve the coating by cleaning up undesired coating material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Weber('463) using the teaching of Nacker ('402) with the expectation of successful results of providing the stent with active agent in a geometric pattern for the purpose of delivery of drug into the body in a precise manner. In regard to the requirement of removing active substance with jets of water or jets of N2, it is the Examiner's position that one of ordinary skill in the art would recognize the functional interchangeability of jets of air with jets of N2 as stated in claims 12 and13, and jets of water as stated in claims 10 and 11.

As for claim 33:

Weber et al. ('463) teach after the powder coating process, the stent is subjected to a heat treatment, for example using IR heating (col.10, lone 41-42).

(7)

Claims 7, 9,11,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al. ('987) as applied to claims 1and 2 above, and further in view of Zhong et al. (US 6,156,373).

Zhong et al. ('987) teach a process of coating a powdered active substance on the selected area and the other area of stent surface and removing active substance on the other area by an etching process. Zhong et al. ('987) do not teach removing the active substance by fitting the stent on a nozzle emitting jets of fluid from the nozzle inside of the stent.

Zhong et al. ('373) teach a method of coating stent (col. 11, line 20-29) and removing the excess coating on the stent by inserting the stent on a tool i.e. nozzle (see fig. 6 and 7) comprising a perforatd tube and emitting gas streams, i.e. jets of fluid from the nozzle and through the inside of the stent.

Both processes concerning remove undesired coating on the stent surface. Zhong et al. ('373) would have reasonably suggested the use of nozzle emitting jets of fluid inside of the stent. It would have been obvious to one having ordinary skill in the art to utilize the nozzle of Zhong et al. ('373) in place of the etching process taught by Zhong ('987), in order to effectively remove the coating on the inner surface of the stent.

As for claims 9, 11, 13:

It is the Examiner's position that one of ordinary skill in the art would recognize the functional interchangeability of jets of air with jets of N2 and jets of water.

(8)

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al ('658).

Schwarz et al ('658) teaches a process for coating stent by depositing a formulation which consists of polymers and biological active materials in the form of powder on entire surface of stent and utilize a mask to coat desired area. Schwarz et el ('658) do not teach removing the undesired powder coating on certain area with two sets of mask. It would have been obvious to one having ordinary skill in the art at the time invention was made to duplicate a process with a second, different mask for different region/design, since it has been held that duplication of the essential working parts of a device involves only routine skill in the art would not involve a patentable step. See M.P.E.P 2144.04 VI B.

(9)

As for claims 14 and 15:

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong et al. ('987).

Zhong et al. ('987) teach a process for precisely depositing the powder of active agents on the selected area and the other area of the surface of a stent, and removing the undesired coating on the other area by etching. Zhong et al. ('987) fail to teach removing the active substance by rubbing the surface of the stent with a support, which has a compliant surface. However, it would have been obvious to one having ordinary skill in the

art to remove the undesired coating on the other region by utilizing a functional equivalent rubbing support to clean up the coating pattern on the stent.

(10)

Claim 40 is rejected under 25 U.S.C. 103 (a) as being unpatentable over Verlee et al. ('773).

Verlee et al. ('773) teach that which is disclosed in the above. Verlee et al. ('773) teach the active substance is (page 5, [0061]) tacrolimus, i.e. FK 506. Additionally, the agents or drug formulations can have various known forms such as solutions, dispersions, pastes and particles. Verlee et al. ('773) further teach the active substance (page 7, [0076]) can be mixed with a suitable binder or polymer to for a coating mixture, which is prepared in higher or lower concentrations of active substance as desired. Verlee et al. ('773) fail to specifically teach the viscosity of the paste of FK506 for the coating process. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the viscosity of the paste with a base of FK506 to the range of 1000,000 to 120,000 cps, in order to provide an effective coating. Since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable ranges involves only routine skill in the art. (See M.P.E.P.2144.05 IIA).

Allowable Subject Matter

There is no allowable subject matter at this time.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Document number A to D listed on Notice of References Cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSIE YL CHANG whose telephone number is 571-272-6466. The examiner can normally be reached on MONDAY TO FRIDAY 7: 00AM TO 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIMOTHY MEEKS can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***

KEITH HENDRICKS
PRIMARY EXAMINER